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Guidance for the Reregistration of Pesticide Products Containing Prometryn as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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DIRECTION DE L'AERODYNAMIQUE

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Janvier 1986

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U.S. DEPARTMENT OF COMMERCE
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SPRINGFIELD, VA 22161

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

March 1987

PB87-184826

Pesticides

EPA

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PROMETRYN

AS THE ACTIVE INGREDIENT

OPP NUMBER 080805

CAS (DOCKET) NUMBER 7287-19-6

MAR 20 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

The following terms are used throughout this Registration Standard and are defined here for the convenience of the reader.

ADI: (Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a complete data base.

A/D Ratio: This ratio determines a level of concern regarding whether effects observed in embryos and fetuses from treated females are "primary" (due to direct compound-related effects) or "secondary" (to maternal toxicity). Thus, the NOEL for maternal effects ("A" numerator) divided by the embryo/fetal NOEL ("D" for "developmental"), including frank terata (gross congenital defects), defines this concern. If A/D is less than "1", developmental toxicity of a substance may be ascribed to secondary effects of maternal toxicity; if greater than 2, the substance is considered a direct (primary) developmental toxicant. Scientific interpretation is required in the range, 1 to 2 (LEL's may be used; or effects from other types of studies, e.g., reproduction).

ai: Active ingredient

CAS: Chemical Abstract Society (number)

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline).

Core Guideline: Studies which satisfy Agency data requirements.

Core Minimum: Studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency guidelines.

Core Supplementary: Studies in this category are scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet guideline requirements and thus do not support registration of a product.

EEC: (Estimated Environmental Concentration) Estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

EP: End-use Product

EPA: The Environmental Protection Agency, also "the Agency"

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

HDT: Highest dose tested

Invalid: Studies which are deficient in some *vital* parameter or those studies which have been judged *not* to be scientifically sound or those studies whose reliability is seriously questioned.

LC_{50}: (median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/L or ppm).

LD_{50}: (median lethal dose): a statistically derived single dose that can be expected to cause death in 50 percent of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number)--EPA's system of tracking studies used in support of registrations

MP: Manufacturing-use product

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level--the maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA)

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

OM: Organic matter (used to describe soils)

ppm: Parts per million

PADI: (Provisional Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure active ingredient

Technical: Active ingredient as manufactured

TMRC: (Theoretical Maximum Residue Contribution) An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg ai/day, assuming a 60 kg person.

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of Chemical

Common Name: Prometryn

Chemical Name: 2,4-bis (isopropylamino)-6-(methylthio)-s-triazine

Other Names: Prometryne, Caparol, G-34161, Gesagard, Primatol Q, Prometrex

CAS Number: 7287-19-6

OPP (Shaughnessy) Number: 080805

Empirical Formula: $C_{10}H_{19}N_5S$

Molecular Weight: 241.4

Description of chemical characteristics: White, odorless, solid powder with a melting point of 118 to 120 °C. The chemical is readily soluble in organic solvents and soluble in water to 33 ppm at 20 °C.

Density: 1.15 ± 0.02 g/cm^3 at 20 °C

Stability: Stable in neutral, slightly acidic or basic media. Half-life at 25 °C of 22.2 days and 1200 days in 0.1 N HCl and 0.1 N NaOH, respectively. Stable for a minimum of 3 years at room temperature.

B. Use Profile

Type of Pesticide: Herbicide

Pests Controlled: Annual broadleaf and grass weeds

Registered Uses: Cotton, celery, pigeon peas, corn, ornamental plants, and forest trees (nursery seed beds)

Predominant Uses: Cotton (approximately 97%)
Celery (approximately 3%)

Mode of Activity: Interferes with electron transport in the plant's photosynthetic process.

Formulation

Manufacturing-Use Products: 95% and 97% active ingredient (technical)

End-Use Products: 80% ai wettable powder; 44.4% (4 lb ai/gal) emulsifiable concentrate; 45.41% (4 lb ai/gal) flowable concentrate.

Methods of Application: Applied broadcast or in a band as a preplant incorporated, a preemergence, a directed postemergence, or a layby spray using ground equipment or aircraft.

III. AGENCY ASSESSMENT

A. Summary of Assessment

Based on the review of the data filed in support of the registration of prometryn, the Agency has reached the following conclusions. A more detailed discussion of the full assessment appears in Section B.

1. Data from acute oral and acute dermal studies indicate that prometryn has low acute toxicity (Toxicity Category III). The chemical falls within Toxicity Category IV for primary dermal irritation.

2. The teratogenic, oncogenic, reproductive, and mutagenic potential cannot be determined until the chronic studies listed in Data Table A are submitted and reviewed.

3. Available data indicate that prometryn has intermediate mobility in sandy loam soils and high mobility in sandy soils. However, degradation, soil field dissipation, leaching, accumulation and metabolism studies are required in order to fully assess the environmental fate of prometryn. Pending the results of soil field dissipation and leaching studies, a ground water monitoring study may be required.

4. Prometryn is not acutely hazardous to birds. It is slightly toxic to freshwater invertebrates and moderately toxic to fish. Prometryn may pose a risk to some endangered plant and animal species. Therefore, phytotoxicity, avian and aquatic organism studies are required. Proposed restrictive labeling for endangered species will be required once the Agency receives concurrence on the assumption of jeopardy, based on the crop cluster, from the U.S. Fish and Wildlife Service.

5. The Theoretical Maximum Residue Contribution (TMRC) for prometryn in the daily diet based on the total tolerances and daily food intake of 1.5 kg is 0.000205 mg/kg/day. Under these conditions 5.13% of the PADI (Provisional Acceptable Daily Intake) has been used.

In the course of its review, the Agency has identified data which are necessary to evaluate risks associated with the use of prometryn. These data must be developed and submitted in order to maintain registrations of products or register new products containing prometryn. Table 1 summarizes the data gaps. Please note that this is only a summary, and more details can be obtained by referring to Data Table A in Appendix I.

The Agency has also determined that certain additional or revised label restrictions are necessary in order for prometryn registrations to remain in compliance with the provisions of FIFRA. These restrictions include a feeding/grazing restriction and an environmental precautions statement.

A more detailed discussion of the Agency's assessments follows. In Part IV, the Regulatory Position and Rationale section details the Agency's position regarding the regulation of prometryn, and Section D of Part IV, Required Labeling, contains the specific wording for label revisions.

TABLE 1

Summary of Data Gaps

Product Chemistry

All product chemistry data

Residue Chemistry

Metabolism studies (plants, livestock)
Residue analytical method (plant & animal residues)
Storage stability
Residue studies

Toxicology

Acute inhalation
Eye irritation
Dermal sensitization
21-Day dermal (rabbit)
Chronic toxicity (rodent)
Oncogenicity (2 species)
Teratology (rat)
Reproduction (rat)
Mutagenicity battery
General metabolism

Fish and Wildlife

Avian dietary (upland gamebird)
Avian reproduction (upland gamebird & waterfowl)
Acute toxicity to estuarine and marine organisms
Fish early life stage and aquatic invertebrate life-cycle
Aquatic organisms accumulation

Plant Protection

Seed germination/seedling emergence
Vegetative vigor
Aquatic plant growth

Environmental Fate

Hydrolysis
Photodegradation (water, soil, air)
Anaerobic soil metabolism
Leaching, adsorption/desorption
Volatility (lab and field)
Soil dissipation
Soil dissipation (long-term)
Rotational crop accumulation (confined and field)
Fish accumulation

B. Toxicology Characteristics

Extensive data gaps exist for prometryn and few definitive conclusions can be made pending receipt and evaluation of additional data. The following assessment is based on the limited data available.

Several long-term studies were performed using formulated end use products. While data on formulated products are not routinely included in Registration Standards, an exception was made in this case since these represent the only long-term studies for prometryn. These studies are discussed under the headings, Chronic Toxicity, Teratogenicity and Reproduction.

Acute Toxicity

Data from acute oral and acute dermal toxicity studies place technical prometryn in Toxicity Category III.* Primary skin irritation data indicate that technical prometryn is not a primary skin irritant (Toxicity Category IV). There are no acceptable acute inhalation, eye irritation or dermal sensitization studies. These studies are required.

Subchronic Toxicity

Data are not available to assess subchronic toxicity. A 21-day dermal study in rabbits using technical prometryn is required.

Chronic Toxicity

A chronic feeding study in rats was performed using a 50WP (wettable powder) formulation (50% ai). The doses tested, 2.5, 12.5, and 62.5 mg ai/kg/day, were too low to elicit toxicity and too few animals were tested. For these reasons, this study was classified Core Supplementary.

A chronic feeding study in dogs tested dosages of 0.0, 0.375, 3.75, and 37.5 mg ai/kg/day, using prometryn 80WP (80% ai). Groups of three male and three female beagle dogs were dosed with prometryn in their feed for 106 weeks.

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* Toxicity Categories are based on the acute toxicity of the chemical (LD_{50} or LC_{50} values) and are used to determine the appropriate signal word and precautionary language for product labeling. Toxicity Category III requires the signal word CAUTION and precautions against swallowing, inhaling, or contact with the skin and eyes, along with appropriate first aid instructions. Toxicity Category IV also requires the signal word CAUTION, but no precautionary statements are required. See 40 CFR 162.10.

Three dogs/sex/group were used instead of the currently recommended four dogs/sex/group, and a minimum of clinical pathology tests were used. Despite these deficiencies, this study was well run and adequately documented and was therefore classified Core Minimum. The only indications of toxicity were found histopathologically and included degenerative hepatic changes, renal tubular degeneration, and bone marrow atrophy. These effects are considered minor since no corresponding anomalies were seen in the clinical pathology tests. The NOEL (no-observable-effect level) for these effects was 3.75 mg ai/kg/day. The LEL (lowest effect level) was 37.5 mg ai/kg/day. This study fulfills the chronic feeding (non-rodent) data requirement.

A chronic feeding study in rodents using technical prometryn is required.

Oncogenicity

There are no oncogenic studies available to assess oncogenicity. Neither the rat nor the dog chronic feeding studies (previously discussed) demonstrated any oncogenic potential. Oncogenic studies in 2 species (rat and mouse) are required.

Teratogenicity

A rabbit teratology study using formulated prometryn (purity not given) tested doses of 0, 2, 12, and 72 mg ai/kg/day. Although the purity is unknown, the Agency believes that the test material did approach the purity of the technical. The results were:

Embryotoxicity NOEL and developmental toxicity
   NOEL > 72 mg ai/kg/day (HDT)
Maternal toxicity NOEL and fetotoxicity
   NOEL = 12 mg ai/kg/day
Maternal toxicity LEL and fetotoxicity
   LEL = 72 mg ai/kg/day
Developmental toxicity index (A/D) = 72/72 = 1

This study was well run and adequately assessed the potential for teratogenicity in rabbits. The study is classified Core Minimum and fulfills the teratology (rabbit) data requirement.

A teratology study in rats using technical prometryn is required.

Reproduction

Data are not available to assess reproductive effects of technical prometryn. One study is available but was performed using prometryn 50WP (50% ai). The doses tested, 0.0, 2.5, and 5.0 mg ai/kg/day, were too low to elicit a toxic effect. The study is classified as Core Supplementary and does not fulfill the data requirement for a 3-generation reproduction study.

A reproduction study in rats using technical prometryn is required.

Mutagenicity

There are no acceptable data to assess mutagenicity. Thus, gene mutation, chromosomal aberration, and direct DNA damage assays are required.

C. Other Science Findings

Environmental Fate

Available data are insufficient to fully assess the environmental fate of prometryn. Data Table A lists the required environmental fate studies. Available data indicate that prometryn has a propensity to leach, has hydrolytic stability, and is persistent in the soil. The leaching studies reviewed (soil columns, soil thin layer chromatography and adsorption/desorption) indicate that prometryn has intermediate mobility in sandy loam soils and high mobility in sandy soils. Mobility appears to be related to organic content of the soil; the lower the organic content, the more mobile prometryn is in the soil. Pending the results of additional required leaching and soil field dissipation studies, a ground water monitoring study may be required.

Exposure

Since the currently available data do not indicate a basis for concern, the Agency is deferring any requirements for exposure data. Should the toxicity studies required in this Standard indicate a concern for human exposure, appropriate exposure data will be required.

Ecological Effects

a. Terrestrial Organisms

Based on available data, technical prometryn is not acutely toxic to birds. An acute oral LD_{50} value was determined to be greater than 4640 mg/kg for mallard ducks. When administered through the diet, prometryn (80% ai) was found to have an LC_{50} value (converted to 100% ai) of 34,512 ppm (5-day exposure) for mallards. The avian dietary LC_{50} Guidelines requirement for upland game birds is unfulfilled, therefore this study is required.

No avian reproduction study was available for evaluation. This study is required because (1) prometryn is expected to be stable in the environment, (2) the pesticide may be stored or accumulated in plant or animal tissues, and (3) prometryn may be applied up to five times (on cotton) thus, permitting repeated or continuous exposure.

There is sufficient information to characterize prometryn as relatively nontoxic to honeybees.

b. Aquatic Organisms

A *Daphnia magna* 48-hour LC_{50} value of 18.59 ppm indicates that technical prometryn is slightly toxic to freshwater invertebrates. Fish acute toxicity data indicate that technical prometryn is moderately toxic to warmwater (bluegill sunfish) and coldwater fish (rainbow trout). Acute LC_{50} values of 10.0 ppm and 2.9 ppm were reported in bluegill sunfish and rainbow trout, respectively.

The aquatic estimated environmental concentration (EEC) calculated by the Agency is 0.25 ppm. Since the EEC is greater than 1% of both freshwater fish and aquatic invertebrate LC_{50} in acute toxicity testing of the technical, a fish early life stage and aquatic invertebrate life-cycle study on the technical are required. The use pattern on corn and cotton triggers concern for exposure to estuarine and marine organisms. Therefore, acute estuarine and marine studies are required to assess the potential hazard to these organisms.

c. Endangered Species

The use of prometryn on corn and cotton may pose a hazard to endangered species. The registered use of this chemical on corn permits a single application, as well as multiple applications. A single application of prometryn per year is not expected to harm most animal species, due to its low toxicity, except by destruction or adverse modification of habitat. However, there is concern for the endangered species, Solano grass and Valley Elderberry longhorn beetle, both of which occur in California, following a single application on corn. Proposed Labeling has been designed to protect these species.

For multiple applications per year, and based on an assumption of jeopardy for the endangered species cluster* information available to the Agency, prometryn was found to pose potential hazards (due to sufficiently high application rates and the half-life of prometryn) to the following endangered species:

> For corn: Everglade kite (potential harm to the apple snail), Mollusks, Scioto madtom, Slackwater darter, Solano grass, Valley Elderberry longhorn bettle (destruction of elderberry wood), Woundfin, Delta Green ground beetle, Kern Primrose sphinx moth.
>
> For cotton: Alabama cavefish, Bayou darter, Comanche Springs pupfish, Fountain darter, Gila topminnow, Mollusks, Leopard darter, San Marcos gambusia, Slackwater darter, Houston toad, Pecos gambusia.

Proposed endangered species labeling has been designed to protect these species when there are multiple applications of prometryn.

The following proposed endangered species labeling is based on an assumption of jeopardy from the crop cluster and will be required once the Agency receives concurrence from the U.S. Fish and Wildlife Service.

a. THE FOLLOWING ENDANGERED SPECIES LABELING FOR CORN USE WITH ONE APPLICATION PER SEASON IS PENDING U.S. FISH AND WILDLIFE SERVICE CONCURRENCE.

"ENDANGERED SPECIES RESTRICTIONS

Use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the counties listed below. The use of this product may pose a hazard to certain Federally-designated endangered species (namely Solano grass and Valley Elderberry longhorn beetle) known to occur in specific areas within the CALIFORNIA counties of Butte, Colusa, Glenn, Merced, Sacramento, San Joaquin, Solano, Tehama, and Yolo. Before using this pesticide in these counties, you must obtain the ENDANGERED SPECIES BULLETIN for the county in which the product is to be used. These bulletins are available from your local pesticide distributor, your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, and the appropriate Regional Office of either the U.S. Fish and Wildlife Service in Sacramento, California or the U.S. Environmental Protection Agency. THESE BULLETINS MUST BE REVIEWED PRIOR TO PESTICIDE USE. USE OF THIS PRODUCT IN A MANNER INCONSISTENT WITH THE ENDANGERED SPECIES BULLETIN IS A VIOLATION OF FEDERAL LAWS."

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* Under the cluster program, the Agency assesses the individual risk to endangered species, from all chemicals within the same use pattern (or "cluster") together.

b. THE FOLLOWING ENDANGERED SPECIES LABELING INFORMATION FOR CORN AND COTTON USES WITH MULTIPLE APPLICATIONS IS PENDING CONCURRENCE FROM THE U.S. FISH AND WILDLIFE SERVICE.

"ENDANGERED SPECIES RESTRICTIONS

Use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the counties listed below. Before using this pesticide in these counties, you must obtain the ENDANGERED SPECIES BULLETIN for the county in which the product is to be used. These bulletins are available from your local pesticide distributor, your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters and the appropriate Regional Office of either the U.S. Fish and Wildlife Service or the U.S. Environmental Protection Agency. THESE BULLETINS MUST BE REVIEWED PRIOR TO PESTICIDE USE. USE OF THIS PRODUCT IN A MANNER INCONSISTENT WITH THE ENDANGERED SPECIES BULLETIN IS A VIOLATION OF FEDERAL LAWS.

ALABAMA
Counties
Colbert, Jackson, Lauderdale, Limestone, Madison, Marshall, Morgan

ARIZONA
Counties
Graham, Maricopa, Mohave, Pima, Pinal, Santa Cruz

ARKANSAS
Counties
Clark, Clay, Cross, Hot Spring, Jackson, Lawrence, Monroe, Poinsette, Polk, Randolph, Sharp, St. Francis, Swier, White, Woodruff

CALIFORNIA
Counties
Butte, Colusa, Glenn, Kern, Merced, Sacramento, San Joaquin, Solano, Tehama, Yolo

FLORIDA
Counties
Broward, Dade, Glades, Indian River, Osceola, Palm Beach, Polk, St. Lucie

KENTUCKY
Counties
Ballard, Edmundson, Green, Jackson, Laurel, Livingston, Marshall, McCracken, Monroe, Pulaski, Rockcastle, Russell, Taylor, Trigg, Warren, Wayne, Whitley

MISSISSIPPI
Counties
Claiborne, Copiah

NEVADA
Counties
Clark

NEW MEXICO
Counties
Chaves, Eddy

OHIO
Counties
Champagne, Franklin, Logan, Madison, Pickaway, Union

OKLAHOMA
Counties
McCurtain, Pushmataha

TENNESSEE
Counties
Benford, Blount, Claiborne, Coffee, Decatur, Franklin, Hancock, Hawkins, Lawrence, Lincoln, Loudon, Marion, Marshall, Maury, Perry, Rhea, Roane, Scott, Sequatchie, Smith, Sullivan, Trousdale, Wayne, Wilson

TEXAS
Counties
Bastrop, Burleson, Comal, Hays, Jeff Davis, Pecos, Reeves

UTAH
Counties
Washington

VIRGINIA
Counties
Lee, Russell, Scott, Smyth, Tazewell, Washington,
Wise"

Prometryn is registered for use on celery and pigeon peas which have not yet been reviewed in the cluster program. It is anticipated that little exposure to threatened and endangered species will occur with these uses.

d. Plant Protection

No plant protection studies were available for review.

Phytotoxicity testing is required on a case-by-case basis to support products that may pose hazards to endangered or threatened species. As previously discussed, prometryn when applied as a preemergent herbicide on corn may pose a hazard to several endangered species including Solano grass and the Elderberry longhorn beetle (an insect which feeds on elderberry wood). Therefore, the following phytotoxicity studies are required: seed germination/seedling emergence, vegetative vigor, and aquatic plant growth.

D. Tolerance Reassessment

Tolerances have been established for residues of prometryn in or on a variety of raw agricultural commodities (40 CFR 180.222). EPA has evaluated the residue and toxicology data supporting tolerances, and has addressed the following regulatory issues:

a. Whether the current tolerances are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA section 24(c) and intrastate uses and methods of applications).

b. Whether group tolerances could be established in accordance with 40 CFR 180.34(f).

c. Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

d. Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in Section IV.A., Regulatory Positions and Rationales.

Residue Data

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of prometryn.

b. Radiolabeled studies on the uptake, translocation and metabolism of prometryn in plants which show that prometryn is absorbed by the roots and is translocated to the foliage.

c. Radiolabeled studies on the metabolism and translocation of prometryn in rats which show that most of the administered $[^{14}C]$ prometryn was excreted in urine and feces. Tissues contained 2.94 to 3.71 percent of the total dosed ^{14}C-activity. ^{14}C-activity was detected in blood, kidney, liver, heart, muscle, fat, and reproductive organs.

d. Analytical methodology for determining the levels of residues of prometryn in plants and animals. Adequate gas chromatographic (GC) and ultraviolet (UV) spectrophotometric methods are available for the collection of data pertaining to residues of prometryn *per se* in or on plant commodities. Neither method has been subjected to a method tryout. The Agency recommends that the gas chromatographic method undergo a method trial (performed by the Agency) to confirm that this method is adequate for enforcement purposes.

e. Storage stability data demonstrating that residues of prometryn are stable in or on pigeon peas for up to 42 days when stored in plastic containers at 10 °F (-12 °C) and in milk stored at -10 °C for up to 28 days.

f. Data on magnitude and levels of residues of prometryn in individual raw agricultural commodities.

Toxicology Data

The toxicology data considered in support of the tolerances include: a chronic feeding study in dogs with a NOEL of 3.75 mg ai/kg/day and a rabbit teratology study with a fetotoxic and maternal NOEL of 12 mg ai/kg/day, and an embryotoxicity and developmental toxicity NOEL of 72 mg ai/kg/day.

The provisional acceptable daily intake (PADI) for prometryn is 0.004 mg/kg/day. The PADI is based on the 2-year dog feeding study. The NOEL was 3.75 mg/kg/day and an uncertainty factor of 1000 was used. An uncertainty factor of 1000 was chosen because (1) it is not clear whether another species will prove to be more sensitive to prometryn than the dog and (2) calculations were based on the inadequate chronic rat data available to the Agency. The PADI of 0.004 mg/kg/day is equivalent to a maximum permissible intake (MPI) of 0.24 mg/day for a 60 kg individual. The theoretical maximum residue contribution (TMRC) of prometryn in the daily diet is 0.000205 mg/kg/day based on the existing tolerances and a daily food intake of 1.5 kg, with 5.13 percent of the PADI being utilized.

Tolerances Issued

The following tolerances have been established for residues of prometryn:

Commodity	Tolerance (ppm)
Celery	0.5
Corn, fodder, field	0.25
Corn, fodder, pop	0.25
Corn, fodder, sweet	0.25
Corn, forage, field	0.25
Corn, forage, pop	0.25
Corn, forage, sweet	0.25
Corn, fresh (inc. sweet K+CWHR)	0.25
Corn, grain	0.25
Cotton	1.00
Cottonseed	0.25
Pigeon peas	0.25

Canadian tolerances have been established for residues of prometryn in or on celery, pigeon peas and corn at 0.1 ppm (negligible residues).

No Mexican or Codex Alimentarius tolerances have been established for prometryn.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITION AND RATIONALE

Based on review and evaluation of all available data and other relevant information on prometryn, the Agency has made the following determinations:

1. The Agency is not initiating a Special Review of prometryn at this time.

   Rationale: Since available data are limited, the Agency is not yet able to make a determination as to whether any of the criteria specified in 40 CFR 154.7 have been met or exceeded.

2. The Agency will not establish significant* new food uses until additional residue chemistry and chronic toxicology data are available to assess existing uses.

   Rationale: It is Agency policy not to establish significant new uses where major data gaps exist. When additional data are evaluated, the Agency will determine whether significant new food uses may be established.

3. The Agency is not imposing any reentry statements nor is it requesting that reentry data be submitted.

   Rationale: No toxicological concerns which would indicate the need for reentry statements or reentry data have been identified at this time. This conclusion is subject to change based on evaluation of required toxicological data.

4. The Agency is proposing endangered species labeling for prometryn products labeled for corn and cotton use. Refer to Section III C, under Endangered Species for proposed labeling requirements.

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*Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in Theoretical Maximum Residue Contribution of greater than 1 percent.

Rationale: The uses, corn and cotton, pose potential hazard to endangered species, based on an assumption of jeopardy for the crop cluster. In order to protect endangered species in areas where prometryn is used on corn and cotton, endangered species labeling will be required once the Agency receives concurrence from the U.S. Fish and Wildlife Service. At that time, a PR (Pesticide Registration) Notice will be issued in order to notify registrants of the final label requirements for endangered species.

5. The Agency is requiring toxicology studies. Refer to the data table in Appendix I for details of toxicology studies required.

   Rationale: Acute, subchronic, chronic, oncogenicity, reproduction, mutagenicity, teratology, and metabolism studies on technical prometryn are required in order to complete the data base for prometryn.

6. The Agency is requiring environmental fate studies on prometryn and may require a ground water monitoring study. Refer to the data table in Appendix I for details of environmental fate studies required.

   Rationale: Available data are inadequate to fully assess the environmental fate of prometryn. Degradation, leaching, accumulation, soil field dissipation and metabolism studies are required. A decision regarding the need for a ground water monitoring study will be made following submission and review of leaching and soil field dissipation studies.

7. The Agency is requiring additional fish and wildlife studies which are necessary to support continued registration of prometryn products. Refer to the data table in Appendix I for details on the fish and wildlife studies required.

   Rationale: Available data are insufficient to fully assess the effects of prometryn on fish and wildlife.

8. The Agency is requiring plant protection studies.

   Rationale: Based on endangered species concerns, phytotoxicity data are required. Refer to the data table in Appendix I for details.

9. The Agency is requiring residue chemistry data on prometryn.

Rationale: The metabolism of prometryn in plants and animals is not adequately understood. Metabolism studies are required in cotton and celery. Metabolism studies utilizing ruminants and poultry are also required. Storage stability and residue data in or on meat, milk, poultry, and eggs are required.

10. The Agency will not require additional residue data on corn, corn forage, corn fodder, pigeon peas and cotton.

Rationale: Sufficient data are available to ascertain the adequacy of the established tolerances.

11. The Agency is requiring crop residue data on celery and processing studies on corn.

Rationale: Available data are insufficient to ascertain the adequacy of the established tolerances for residues on celery. Storage stability and plant metabolism data must be submitted prior to magnitude of residue data on celery and corn. Processing studies on corn are required.

12. The Agency has determined that the following revisions in the tolerances listed in 40 CFR 180.222 are necessary and will initiate actions to effect these changes.

- The entries "corn fodder, sweet" and "cotton" must be deleted from 40 CFR 180.222.
- The tolerance expression should include the parent compound and all triazine-containing analogs and metabolites which are of toxicological concern.

Rationale:

- "Corn fodder, sweet" is not considered a raw agricultural commodity of sweet corn. This term is a misnomer since corn fodder is harvested at a different time interval than sweet corn. A feeding/grazing restriction is currently in effect for cotton forage, thus the entry "cotton" (presumably intended to cover cotton forage) must be deleted.
- Established tolerances are based on the parent compound only. All triazine-containing analogs and metabolites of toxicological concern must be included in the tolerance expression. The

toxicological relevance of the 11 impurities representing 3% of the 97% technical, cannot be determined until mammalian metabolism and quantitative product chemistry data are submitted.

13. Crop group tolerances are not being established at this time.

    Rationale: Crop group tolerances are not appropriate at the present time due to a lack of proposed use directions and appropriate supporting residue data.

14. The Agency has identified certain data that will receive immediate review when submitted.

    Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

    §158.130 Environmental Fate

    163-1 Leaching and Adsorption/Desorption
    164-1 Soil Field Dissipation

15. While data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing prometryn as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

    Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7).

    Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain prometryn as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain prometryn as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing prometryn provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, technical grade or manufacturing-use products containing prometryn must be labeled for formulation into end-use products registered only for the uses listed in Appendix III, EPA Index to Pesticide Chemicals--Prometryn. This Index lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All MPs (and EPs if covered by this Standard) must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing prometryn may be released for shipment by the registrant after May 1, 1988, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing prometryn may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after May 1, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

In addition, to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for MPs must list the active ingredient as:

"Prometryn: 2,4-bis(isopropylamino)-6-(methylthio)-
s-triazine"

2. Use Pattern Statement

All technical grade and manufacturing-use products shall state that they are intended only for formulation into end-use products registered for one or more of the uses listed in the EPA Index to Pesticide Chemicals for Prometryn, Appendix III. However, no use may be included on the label if the registrant fails to agree to comply with data requirements in Table A for that use pattern.

3. Precautionary Statements

The following statement shall appear on manufacturing-use products:

> "Do not discharge effluent containing technical grade or manufacturing-use products containing prometryn into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or the Regional Office of EPA."

All end-use products shall bear the following statements:

a. Feeding/Grazing Restriction

"Do not allow livestock to feed or graze on treated cotton crops."

b. Environmental Precautions

"Do not apply directly to water
or wetlands (swamps, bogs, marshes,
and potholes). Do not contaminate
water by cleaning of equipment
or disposal of wastes."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Prometryn as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Prometryn in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Prometryn as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing Prometryn either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Robert J. Taylor, PM-25
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A and B contains listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

   TGAI = Technical grade of the active ingredient
   PAI = Pure active ingredient
   PAIRA = Pure active ingredient, radio labeled
   TEP = Typical end use formulation
   MP = Manufacturing use product
   EP = End use product

   Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

   A = Terrestrial, food
   B = Terrestrial, non-food
   C = Aquatic, food
   D = Aquatic, non-food
   E = Greenhouse, food
   F = Greenhouse, non-food
   G = Forestry
   H = Domestic outdoor
   I = Indoor

   Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

   YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

   PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitted, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

   NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate No. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]/	Bibliographic Citation[1]/	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	N/A	N/A	Yes[2]/[3]/	6 Months
61-2 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes[4]/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	N/A	N/A	Yes[5]/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	N/A	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (Continued)						
63-6 - Boiling Point	TGAI	All	N/A[6]	N/A	No	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	N/A	N/A	Yes[7]	6 Months
63-8 - Solubility	TGAI or PAI	All	N/A	N/A	Yes[8]	6 Months
63-9 - Vapor Pressure	PAI	All	N/A	N/A	Yes[9]	6 Months
63-10 - Dissociation Constant	PAI	All	N/A	N/A	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	N/A	N/A	Yes	6 Months
63-12 - pH	TGAI	All	N/A[10]	N/A	No	
63-13 - Stability	TGAI	All	N/A	N/A	Yes	6 Months
Other Requirements:						
64-1 - Submittal of Samples	TGAI, PAI	All	N/A	N/A	No	

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

(Footnotes continued on next page)

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN
FOOTNOTES (cont'd)

§158.120 Product Chemistry

2/ Details of the manufacturing process, including the relative amounts of beginning materials, a description of equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures for EPA Registration Nos. 100-542, 2749-278, 46386-2, and the unregistered 97% technical are required.

3/ The name and address of manufacturer, producer, or supplier of each beginning material used to manufacture EPA Registration Nos. 100-542, 2749-278, 46386-2, and the unregistered 97% technical are required. Also, a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes the composition and properties must be submitted.

4/ A discussion of each impurity believed to be present at 0.1% or more based on knowledge of the beginning materials, all possible chemical reactions and any contamination is required.

5/ Five or more representative samples of the registered technicals must be analyzed for prometryn. In addition, five or more representative samples must be analyzed for each impurity present at 0.1% or more (w/w) and each additional "toxicologically significant" impurity by analytical methods supported by validation studies of their precision and accuracy. The Agency determines what is "toxicologically significant" based on the results from the data required in 61-3 and 62-1.

6/ Not applicable since the technical is a solid at room temperature.

7/ Density, bulk density, or specific gravity must be determined at 20 °C or 25 °C.

8/ Solubility in representative polar and nonpolar organic solvents must be reported in g/100 ml, ppm, or similar terms and must be determined at 20 °C or 25 °C.

9/ Vapor pressure must be determined at 25 °C.

10/ Not applicable since the technical cannot be dispersed with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity1/	TGAI				
171-3 - Directions for Use	--	Yes	Product Label	No	
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00022855,00023213, 00024378,00055672, 00093542,00125011, 00125013	Yes2/3/4/	18 Months
- Livestock	PAIRA	Partially	00093337,00093338, 00093339	Yes3/5/	18 Months
171-4 - Residue Analytical Method					
- Plant Residues	TGAI	Partially	00024779,00027330, 00056556,00105780, 00106829,00121720, 00123218,00125011, 00125015,05016141	Yes6/7/	18 Months
- Animal Residues	TGAI & Metabolites	Partially	00023280,00093535, 00093536,00121720	No8/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry (continued)					
171-4 - Storage Stability	PAI	Partially	00093535,00121720	Yes[4]/[9]/	18 Months
171-4 - Magnitude of the Residue - Residue Studies					
Crop Field Trials[10]/					
Leafy Vegetables Group[11]/					
- Celery	EP	Partially	00034043,00093529, 00093548	Yes[12]/	36 Months
Legume Vegetables Group[13]/					
- Pigeon Peas	EP	Yes	00125015	No[14]/	
Cereal Grains Group[15]/					
- Corn (Field, Sweet and Popcorn)	TEP	Partially	00024696,00093530	Yes[16]/	36 Months
Forage, Fodder, and Straw of Cereal Grains Group[17]/					

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry (continued)					
- Corn Forage and Fodder[18]	TEP	Yes	00024696,00093530, 00125012	No	
171-4 - Magnitude of the Residue - Residue Studies					
Crop Field Trials Miscellaneous Commodities					
- Cottonseed[19]		Yes	00027329,00027330, 00056556,00065048, 00093531,00105780, 00106358,00106481, 00106829,00125011	No	
- Meat/Milk/Poultry/ Eggs		Partially	00093535,00093536	Reserved[20]	

1/ Refer to Product Chemistry Data Requirement table.

2/ Cotton and celery are to receive postemergence soil applications of [^{14}C]prometryn at or above the maximum registered rate under conditions comparable to those specified in the label directions. Uptake, distribution, and metabolism of prometryn must be characterized. Terminal residues in or on mature plant parts must be identified and quantified. Residue identification must be confirmed by a method such as GC, HPLC, and/or mass spectrometry. Submitted data must also depict efficiency of extraction procedures.

3/ Metabolism data should be submitted prior to completion and submission of residue data, since the data required for individual commodities are dependent on metabolism data.

4/ Storage stability and plant metabolism data are required prior to submitting magnitude of residue data on celery and corn.

(Footnotes continued on the next page)

§158.125 Residue Chemistry (continued)

5/ Ruminants and poultry are to be dosed for at least 3 days with ring-labeled [^{14}C]prometryn at a concentration in the total diet that will result in sufficient residues in tissues, milk, and eggs for characterization. Animals are to be sacrificed within 24 hours of the final dosing. Milk and eggs must be collected twice daily. ^{14}C-Residues in muscle, fat, kidney, liver, milk, and eggs must be characterized. Samples from requested metabolism studies must also be analyzed using accepted enforcement methods.

6/ Submit an acceptable analytical procedure for enforcement of prometryn tolerances in the various commodities of concern.

7/ If the requested data regarding the nature of the residue in plants reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required.

8/ Data are not required at the present time since there are no tolerances for residues of prometryn in animal commodities.

9/ Details of storage intervals and conditions of samples used to support all established tolerances for residues of prometryn must be submitted. These data must be accompanied by data depicting the percent decline in residues at the time and under the conditions specified. It should also be noted that all residue data requested in this standard must be accompanied by data regarding storage intervals and conditions of sample storage. These data must be accompanied by fortification recovery data depicting the stability of prometryn residues of concern in appropriate sample substrates under the conditions and for the time intervals specified.

10/ If requested plant metabolism studies reveal the presence of additional metabolites of concern, then data will be required depicting residues of these metabolites in or on treated foods or feeds. The crop group conclusions stated below address only the minimum residue chemistry data base acceptable for purposes of establishing a group tolerance. The registrant should consider the complete data requirements stated in the 40 CFR 180.34 if they elect to propose crop group tolerances.

11/ Should the registrant seek a crop group tolerance, proposed use directions and supporting residue data must be submitted for residues of prometryn in or on lettuce (head and leaf) and spinach. Also, additional data are required to support the existing tolerance for prometryn in or on celery.

12/ Data must be submitted depicting prometryn residues in or on celery harvested at maturity following a single posttransplant application of, in separate tests, the 4 lb/gal EC at: (i) 3.2 lb ai/A in HI; (ii) 2 lb ai/A in CA and either MI, OH, or WI; and (iii) 1.6 lb ai/A in FL.

13/ Should the registrant seek a crop group tolerance, proposed use directions and appropriate supporting residue data must be submitted for beans (Phaseolus spp., one succulent variety and one dried variety), and soybeans.

14/ No additional data are required for pigeon peas since no detectable residues were observed in peas or pods treated at a 1.1X rate.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

§158.125 Residue Chemistry (continued)

15/ Should the registrant seek a crop group tolerance, proposed use directions and supporting residue data must be submitted for rice, sorghum, and wheat.

16/ Data must be submitted which depict the potential for concentration of prometryn residues of concern during processing of crude oil, refined oil, starch, grits, meal, and flour derived from treated field corn grain bearing measurable weathered residues. If the data indicate a potential for concentration of residues in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

17/ If the registrant seeks a crop group tolerance, use directions must be proposed and appropriate supporting residue data submitted for forage of wheat and one other cereal grain crop.

18/ The Agency will initiate action to delete the entry "corn fodder, sweet" since this item is not considered a raw agricultural commodity of sweet corn.

19/ The Agency will initiate action to delete the entry "cotton" since a feeding restriction is currently in effect for cotton forage.

20/ No conclusions can be reached at this time as to the magnitude of residues of prometryn in animal products because the magnitude of the residue in feed items, metabolism in plants, and metabolism in animals are not adequately defined. Upon receipt of these data the Agency will determine the necessity of tolerances in animal products, and may require submission of these data.

TABLF A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	TGAI	A	Yes	00060646,00060314	No	
81-2 - Acute Dermal	TGAI	A	Yes	00060647,00060315	No	
81-3 - Acute Inhalation - Rat	TGAI	A	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	A	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	A	Yes	00060649,00060316	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	N/A		No[1]/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding:						
- Rodent, and	TGAI	A	No		No[2]/	
- Nonrodent	TGAI	A	No		No[3]/	
82-2 - 21-Day Dermal - Rabbit	TGAI	A	No		Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	A	No		No[4]/	
82-4 - 90-Day Inhalation - Rat	TGAI	A	No		No[4]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology (continued)						
82-5 - 90-Day Neurotoxicity:						
- Hen	TGAI	A	N/A		No1/	
- Mammal	TGAI	A	N/A		No1/	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:						
- Rodent, and	TGAI	A	No		Yes	50 Months
- Nonrodent (Dog)	TGAI	A	Yes	00042794 5/	No	
83-2 - Oncogenicity - 2 species:						
- Rat (preferred), and	TGAI	A	No		Yes	50 Months
- Mouse (preferred)	TGAI	A	No		Yes	50 Months
83-3 - Teratogenicity - 2 species:						
- Rat	TGAI	A	No		Yes	15 Months
- Rabbit	TGAI	A	Yes	00157995 5/	No	
83-4 - Reproduction - Rat 2-generation	TGAI	A	No		Yes	39 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology (continued)						
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A	No		Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A	No		Yes	12 Months
84-4 - Other Genotoxic Effects	TGAI	A	No		Yes	12 Months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A	No		Yes	24 Months

1/ This study is not required since the test article is not an organophosphate.

2/ Subchronic feeding data need not be submitted since chronic studies in the rat are required. However, the Registrant should be aware that subchronic studies are useful and often necessary in determining the maximum tolerated dose (MTD) used for oncogenicity studies in rodents (mice and rats).

3/ A subchronic nonrodent feeding study is not required since an acceptable chronic dog feeding study was submitted.

4/ Additional data are not required because of the nature of the exposure pattern.

5/ This study was performed using formulated prometryn. The study is acceptable and fulfills this data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		Yes[1]/	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	00148338	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	--	No		No[2]/	
162-4 - Aerobic Aquatic	TGAI or PAIRA	--	No		No[2]/	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Yes[1]/	12 Months
163-3 - Volatility (Field)	TEP	A	No		Yes[1]/	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.130 Environmental Fate (continued)						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	--	No		No[2]/	
164-3 - Forestry	TEP	--	No		No[2]/	
164-5 - Soil, Long-term	TEP	A	No		Yes[3]/	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A,B	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A,B	No		Yes	50 Months
165-3 - Irrigated Crops	TEP	--	No		No[2]/	
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	--	No		No[2]/	
SPECIAL STUDIES:						
Ground water monitoring	TEP	A,B	No		Reserved[4]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

§158.130 Environmental Fate - Continued

1/ Required based on product use pattern and other pertinent factors such as the results of toxicological data (i.e., acute inhalation studies).

2/ Not required based on currently registered use patterns.

3/ Required because pesticide residues do not readily dissipate in soil.

4/ Pending the results of acceptable leaching and soil field dissipation studies, a ground water monitoring study may be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	Yes	00082966	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird	TGAI	A,B	No		Yes	9 Months
- Waterfowl	TGAI	A,B	Yes[1]/	00070686	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B	No		No[2]/	
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	A,B	No		Yes[3]/	24 Months
- Waterfowl	TGAI	A,B	No		Yes[3]/	24 Months
71-5 - Simulated Field Testing						
- Mammals	TEP	A,B	No		No[2]/	
- Birds	TEP	A,B	No		No[2]/	
- Actual Field Testing						
- Mammals	TEP	A,B	No		No[2]/	
- Birds	TEP	A,B	No		No[2]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms (continued)						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity						
- Coldwater Fish Species	TGAI	A,B	Yes	00070686	No	
	TEP	A,B	Yes	00121154,00024738	No	
- Warmwater Fish Species	TGAI	A,B	Yes	00070686	No	
	TEP	A,B	Yes	00121155,00040692	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	Yes	00070146	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A,B	No		Yes[4]/	12 Months
- Mollusk	TGAI	A,B	No		Yes[4]/	12 Months
- Shrimp	TGAI	A,B	No		Yes[4]/	12 Months
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle						
- Freshwater	TGAI	A	No		Yes[5]/	15 Months
- Estuarine	TGAI	A	No		Reserved[6]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms (continued)						
72-5 - Fish Life-Cycle						
- Freshwater	TGAI	A	No		Reserved[7]	
- Estuarine	TGAI	A	No		Reserved[7]	
72-6 - Aquatic Organism Accumulation						
- Crustacean	TGAI	A	No		Yes	12 Months
- Fish	TGAI	A	No		Yes	12 Months
- Insect Nymph	TGAI	A	No		Yes	12 Months
- Mollusk	TGAI	A	No		Yes	12 Months
72-7 - Simulated Field Testing						
- Aquatic Organisms	TEP	A	No		No[2]	
- Actual Field Testing						
- Aquatic Organisms	TEP	A	No		No[2]	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN
FOOTNOTES

§158.145 Wildlife and Aquatic Organisms (continued)

1/ The LC_{50} value from a study using 80.7% ai was adjusted to 100% active ingredient, to fulfill this requirement.

2/ Available information on this chemical and its use patterns indicate the study is not required.

3/ Required based on the potential for repeated exposure; ability to be bioaccumulated (Kow of 2880); and the pesticide is expected to be stable in the environment.

4/ Required to support crop uses associated with coastal counties, specifically cotton and corn.

5/ Required because the estimated environmental concentration in water is greater than 0.01 of the LC_{50} for rainbow trout and Daphnia magna, using technical prometryn.

6/ Reserved pending the results of estuarine acute studies.

7/ Reserved pending the results of freshwater and marine fish early life stage studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	A	No		No[1]/	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		Yes	9 Months
122-1 - Vegetative Vigor	TGAI	A	No		Yes	9 Months
122-2 - Aquatic Plant Growth	TGAI	A	No		Yes	9 Months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		Reserved[2]/	
123-1 - Vegetative Vigor	TGAI	A	No		Reserved[2]/	
123-2 - Aquatic Plant Growth	TGAI	A	No		Reserved[2]/	
TIER III						
124-1 - Terrestrial Field	TEP	A	No		Reserved[3]/	
124-2 - Aquatic Field	TEP	A	No		Reserved[3]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN
FOOTNOTES

§158.150 Plant Protection

1/ Available information on this chemical and its use patterns indicate the study is not required.
2/ Reserved pending results of Tier I phytotoxicity tests.
3/ Reserved pending results of Tier II phytotoxicity tests.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey Bee Acute Contact Toxicity	TGAI	A,B	Yes	00036935	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B	No		No[1]/	
141-4 - Honey Bee Subacute Feeding Study	Reserved[2]/					
141-5 - Field Testing for Pollinators	TEP	A,B	No		No[1]/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[3]/					
142-1 - Aquatic Insect Life Cycle Study	Reserved[3]/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[3]/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	Reserved[3]/					

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN
FOOTNOTES

§158.155 Nontarget Insect (continued)

1/ As data from the acute study indicate low toxicity to honey bees, no further testing is required.
2/ Reserved pending development of test methodology.
3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No		No[1]	
132-1 - Soil Dissipation	TEP	A	No		No[1]	
133-3 - Dermal Exposure	TEP	A	No		No[1]	
133-4 - Inhalation Exposure	TEP	A	No		No[1]	

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[1] Not required because this chemical is classified as Toxicity Category III.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes[2][3]	6 Months
61-2 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes[4]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	N/A	Yes[5]	12 Months
62-2 - Certification of Limits	MP	All	No	N/A	Yes[6][7]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	No	N/A	Yes[8]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	N/A	Yes	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes	6 Months
63-4 - Odor	MP	All	No	N/A	Yes	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes[9]/	6 Months
63-12 - pH	MP	All	No	N/A	No[10]/	
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes	6 Months
63-15 - Flammability	MP	All	No	N/A	Yes	6 Months
63-16 - Explodability	MP	All	No	N/A	Yes	6 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes	15 Months
63-18 - Viscosity	MP	All	No	N/A	Yes	6 Months
63-19 - Miscibility	MP	All	No	N/A	Yes	6 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes	6 Months
Other Requirements:						
64- 1 - Submittal of samples	MP	All	No	N/A	No	

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

FOOTNOTES CONTINUED ON NEXT PAGE

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROMETRYN

§158.120 Product Chemistry (continued)

2/ Details of the manufacturing process, including the relative amounts of beginning materials, a description of equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures for EPA Registration Nos. 100-542, 2749-278, 46386-2, and the unregistered 97% technical are required.

3/ The name and address of manufacturer, producer, or supplier of each beginning material used to manufacture EPA Registration Nos. 100-542, 2749-278, 46386-2, and the unregistered 97% technical are required. Also, a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes the composition and properties must be submitted.

4/ A discussion of each impurity believed to be present at 0.1% or more based on knowledge of the beginning materials, all possible chemical reactions and any contamination is required.

5/ Five or more representative samples of the registered technicals must be analyzed for prometryn. In addition, five or more representative samples must be analyzed for each impurity present at 0.1% or more (w/w) and each additional "toxicologically significant" impurity by analytical methods supported by validation studies of their precision and accuracy. The Agency determines what is "toxicologically significant" based on the results from the data required in 61-3 and 62-1.

6/ Upper and lower limits must be validated and certified for prometryn, and upper limits must be validated and certified for each impurity present at ≥ 0.1% (w/w) for EPA Registration Nos. 100-542, 2749-278, and 46386-2. Certifications should be submitted on EPA Form 8570 Rev. 2-85.

7/ All N-nitrosamines must be identified and quantified in six samples of each technical (registered and unregistered); two samples each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for each nitrosamine found.

8/ Quantitative methods to determine all impurities where a certified limit is required. Each method must be accompanied by validation studies of the precision and accuracy of the method.

9/ Density, bulk density, or specific gravity must be determined at 20 °C or 25 °C.

10/ Not applicable since the technical cannot be dispersed with water.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROMETRYN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A	Yes	00060646,00060314	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A	Yes	00060647,00060315	No	
81-3 - Acute Inhalation Toxicity - Rat	MP	A	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	A	Yes	00060649,00060316	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	A	No		Yes	9 Months

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

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EPA Index to Pesticide Chemicals

PROMETRYN

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PROMETRYN*

TYPE PESTICIDE: Herbicide

FORMULATIONS:
Tech (95%, 97%)
WP (40%, 80%)
EC (4 lb/gal or 44.4% a.i.)
FlC (4 lb/gal or 45.41% a.i.)
SC/L (1 lb/gal or 8.4% a.i.)

GENERAL WARNINGS AND LIMITATIONS: A selective herbicide used to control annual grasses and broadleaf weeds. When applied before weeds emerge, its effectiveness depends on rainfall or irrigation to move it into the soil. Very dry soil conditions require shallow cultivation or rotary hoeing for effective weed control. Use conventional spray equipment with hydraulic or mechanical agitation except in AZ and CA where only mechanical agitation is recommended. In cotton, trifluralin may be applied (before January 1) prior to a preplant incorporated application of prometryn. To avoid spray drift, do not apply under windy conditions. Avoid spray overlap, as crop injury may occur. Do not apply directly to lakes, streams, or ponds. Do not enter treated areas without protective clothing until sprays have dried. For band treatments reduce dosages proportionally.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibition of photolysis of water in the photosynthetic process and inhibition of oxidative phosphorylation.

BROADLEAF WEEDS CONTROLLED:

PBFDCBC	Annual sowthistle	(e)
PEWAIBE	Black nightshade	
PAZAAAC	Chickweed	(e)
PBFDQAA	Cocklebur	(a)
PEDADBA	Common purslane	(d)
PEDABBA	Desert rockpurslane	(e)
PEAAHAA	Dock (seedling)	(b)
PARABAA	Fiddleneck	(e)
PBZABAA	Filaree	(e)
PEMAEBB	Florida pusley	
PEWAAAB	Groundcherry	
PADACBA	Horse purslane	(f)
PBGAFAA	Ipomoea	(d)
PEWADBD	Jimsonweed	(f)

*Caparol
2,4-bis(isopropylamino)-6-(methylthio)-s-triazine

DRAF

BROADLEAF WEEDS CONTROLLED (continued)

PBDAEAB	Lambsquarter	
PBKBDBB	London rocket	(e)
PDAAHAA	Mallow	
PBKAAAC	Mustards	(e)
PBGAFAB	Perennial morningglory	(d)
PAAAABI	Pigweed	
PBFCKBB	Pineappleweed	(e)
PBFBUBF	Prairie sunflower	(c)
PDAAJBF	Prickly sida	
PBVAGBQ	Prostrate spurge	(d)
PAAAABP	Purslane	
PBFAEAA	Ragweed	
PAFACBI	Redroot pigweed	
PBKAHBA	Shepherdspurse	(e)
PEAAGAD	Smartweed	
PBVAGAA	Spurge	(f)
PDAACBA	Spurred anoda	(c)
PZAAABP	Tall morningglory	
PZAAAHA	Wild spiderflower	(f)

(a) Controls shallow germinating seedlings.
(b) Controls winter weeds in TX.
(c) Partial control in NM and west TX.
(d) In SLN site.
(e) Controls winter weeds in CA.
(f) In pigeon peas.

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCAAAAB	Annual grasses	(d)
PCABHBB	Barnyardgrass	
PCQATBA	Coffeeweed	(a)
PCABFAA	Crabgrass	
PCACUAA	Foxtail	
PCABIBA	Goosegrass	
PCOAFBA	Henbit	(b)
PCABHBA	Junglerice	
PCABFBF	Large crabgrass	(d)
PCACEAA	Panicum spp.	
PCACKBH	Rough blackfoot	(c)
PCAAWAA	Sandbur	(a)
PCAARAA	Signalgrass	
PCAAOBB	Wild oats	

(a) Controls shallow germinating seedlings.
(b) Controls winter weeds in TX.
(c) Partial control in NM and west TX.
(d) In SLN site.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
/13002AA	Celery	0.5 ppm General Information: Use the lower dosage on coarse textured soils and soils low in organic matter, and the higher dosage on fine textured soils and soils high in organic matter. The following rotational crops may be seeded 5 months after applying no more than 2 pounds active ingredient per acre: cabbage, celery, corn, okra, onions, peas, and red beets.
	1.2-1.6 (80% WP) 000100-00471 (4 lb/gal EC) 002749-00503 (4 lb/gal FlC) 001812-00274	Use limited to CA. Preemergence. Broadcast. Apply to direct-seeded celery in 20 to 40 gallons of water per acre at planting or shortly after planting before celery emerges. Make 1 application per year. Do not use on sand or loamy soil. Do not apply if crop is under water stress. Do not apply within 2 weeks after application of an herbicidal oil.
	0.8-1.0 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to CA. Postemergence. Broadcast. Apply to direct-seeded celery in 20 to 40 gallons of water per acre after celery has reached the 2 to 5-true leaf stage but before weeds are 2 inches tall. Apply only after foliar applications of other pesticides are dry. Do not use on sandy soils. Do not apply if crop is under water stress. Do not apply within 2 weeks after application of an herbicidal oil.
	0.6-0.8 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to FL. Postemergence. Broadcast. Apply to seedbeds in 20 to 40 gallons of water per acre after celery reaches the 2 to 5-true leaf stage. Make 1 application per year after seedbed covers have been removed for at least 1 week.
	1-2 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to CA. Posttransplant. Broadcast or band. Apply in 20 to 40 gallons of water per acre 2 to 6 weeks after transplanting but before weeds are 2 inches tall. Do not make more than 1 application per crop.

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Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Celery (continued)	
0.8-1.6 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to sandy or mucky soils of FL. Posttransplant. Broadcast or band. Apply in 20 to 40 gallons of water per acre 2 to 6 weeks after transplanting but before weeds are 2 inches tall. Do not make more than 1 application per crop.
1.6-3.2 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to HI. Posttransplant. Broadcast or band. Apply in 20 to 40 gallons of water per acre 2 to 6 weeks after transplanting but before weeds are 2 inches tall. Do not make more than 1 application per crop.
1-2 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to fine textured or mucky soils in MI and OH. Posttransplant. Broadcast or band. Apply in 20 to 40 gallons of water per acre 2 to 6 weeks after transplanting but before weeds are 2 inches tall. Do not make more than 1 application per crop.
1.6-2 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to fine textured soils in WI. Posttransplant. Broadcast or band. Apply in 20 to 40 gallons of water per acre 2 to 6 weeks after transplanting but before weeds are 2 inches tall. Do not make more than 1 application per crop.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/28005AA	Corn	0.25 ppm (corn, field, fodder) 0.25 ppm (corn, field, forage) 0.25 ppm (corn, fresh (incl. sweet) (K+CWHR)) 0.25 ppm (corn, grain) 0.25 ppm (corn, pop, fodder) 0.25 ppm (corn, pop, forage) 0.25 ppm (corn, sweet, fodder) 0.25 ppm (corn, sweet, forage) General Information: Do not use on eroded hillsides as injury to corn may occur. Do not use on corn grown on alkaline calcareous soils in western MN and western IA or in the high plains and intermountain areas of the west where rainfall is sparse. The following rotational crops may be planted 15 months after treatment: cotton, navy beans and other large seeded legumes, oats and other spring-seeded small grains, potatoes, sorghum, and soybeans.
	[MAI] 0.8-1.5 (40% WP) 000100-00492	Preemergence. Broadcast, at planting or band. Apply at planting or immediately after before corn emerges. Apply in 20 to 40 gallons of water per acre. Use the lower dosage on light-textured soils and soils low in organic matter and the higher dosage on heavier soils and soils high in clay or organic matter. Do not use on sandy or loamy soils, peats, muck or highly organic clay soils. Formulated with atrazine.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
28007AA	Cotton	0.25 ppm (cotton, seed) 1.0 ppm (cotton, forage Do not feed treated forage to livestock or graze treated areas. General Information: Do not use in cut areas of newly leveled fields, in areas of excess salt, or in areas where flooding of beds is likely to occur. Do not plant cotton in tractor wheel depressions. On mulch planted cotton, water back only after cotton seedlings are well established. In NM, apply either preplant incorporated or preemergence. Do not use on glandless cotton varieties. Do not treat cotton under stress from drought, cultivation damage, or fertilizer application. Apply in 20 to 40 gallons of water per acre. For preplant and preemergent applications, do not use on sand or loamy sand soil. Use the higher dosage on finer textured soil. Preemergence application to cotton planted in furrows more than 2 inches deep may only be made in bands as wide as the width of the bottom of the furrow. If necessary, cotton may be replanted in soil treated with prometryn, but do not make a second preemergence application. The following rotational crops may be fall planted when prometryn has been applied by preplant incorporation as a preemergent, or as a single postemergent treatment at the rate of 0.48 to 0.64 pound active ingredient per acre: cabbage, okra, onions, peas, red beets, sweet corn and cover crops of oats, sorghum, winter barley, winter rye, and winter wheat. Cover crops must be plowed down and not used for food or feed. If more than 1 postemergent application of 0.48 to 0.64 pound active ingredient per acre is used or if combinations of preemergent and postemergent applications are used, fall seeded crops should not be planted. Spring seeded crops in CA and AZ and spring vegetables in the Rio Grande Valley of TX should not be planted until after April 1. Use aerial application in furrow irrigation cotton only. Apply where broadcast applications are specified (except CA) in a minimum of 5 gallons of total spray per acre.

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Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Cotton (continued)	
1.2-2.4 (80% WP) 000100-00471 (4 lb/gal EC) 002749-00503 (4 lb/gal FlC) 001812-00274 [SLN] 1.2-2.4 (80% WP)	Use limited to AZ, CA, and NM. Preplant incorporation. Broadcast or band. Apply in 10 gallons of water per acre by ground or 5 gallons of water per acre by air. Do not use on sandy soils, in cut areas of newly leveled fields, in areas of excess salt, or in areas where flooding is likely. In NM, apply either preplant or preemergent.
1.2-2.4 (80% WP) (4 lb/gal EC)	Use limited to CA. Preplant incorporation. Broadcast or band. Apply after the initial irrigation but before spring planting. Knock off the top one-third to one-half of the seedbed and incorporate into the soil with a power tiller or a rolling cultivator. Do not cultivate treated soil back toward the cotton until cotton emergence and just before the first irrigation.
1.2-2.4 (80% WP) (4 lb/gal EC) (4 lb/gal FlC) [SLN] 1.2-2.4 (80% WP)	Use limited to AZ, CA, NM, and the upper and lower El Paso Valley of TX. Preplant incorporation. Broadcast or band. Apply to partially finished or finished beds. Apply in 10 gallons of water per acre by ground or 5 gallons of water per acre by air. Tank mix with pendimethalin.
1.2-2.0 (80% WP) (4 lb/gal EC) (4 lb/gal FlC) [SLN] 1.2-2.0 (80% WP)	Use limited to AZ, CA, NM, and the upper and lower El Paso Valley of TX. Preplant incorporation. Broadcast or band. Apply to flat soil before disking in 20 gallons of water per acre by ground or 5 gallons of water per acre by air. Use less than 1.6 pounds active ingredient per acre in AZ and CA. Tank mix with treflan.
1.6-2.0 (80% WP) (4 lb/gal EC)	Use limited to CA. Postbedding. Broadcast or band. Apply before weeds emerge or to weeds less than 2 inches tall. For postemergence weed control add a surfactant or an emulsifiable oil.

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Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Cotton (continued)	
0.6-0.8 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the Gulf Coast and Blacklands of TX. Postbedding. Broadcast or band. For control of winter weeds apply in the fall or winter to fields to be planted to cotton the following spring. For control of emerged henbit add a surfactant or an emulsifiable oil.
1.2-2.4 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the Blacklands of TX and OK, TX Gulf Coast and the TX Coastal Bend. Preemergence. Broadcast or band. Apply at or shortly after planting.
0.8-1.6 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the high plains, rolling plains, and Edward Plateau of TX, southwest TX, and NM. Preemergence. Broadcast or band. Apply at or shortly after planting.
1.6-2.8 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the mid-south and southeast United States other than the Mississippi River Delta in MS. Preemergence. Broadcast or band. Apply at or shortly after planting. In AZ, apply to sharkey clay soil only.
2.0-2.8 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the Mississippi River Delta in MS. Preemergence. Broadcast or band. Apply at or shortly after planting. Do not use on sharkey clay soils.
1.6-2.4 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the Rio Grande Valley of TX. Preemergence. Broadcast or band. Apply at or shortly after planting.
0.48-0.64 (80% WP) (4 lb/gal EC) (4 lb/gal FlC) [MAI] 0.25 (1 lb/gal SC/L) 000100-00495	Postemergence. Directed spray. Apply to cotton 6 or more inches tall. Apply in 10 to 40 gallons of water per acre. For emerged weed control add a compatible surfactant. Leaf fenders or shields may be necessary to prevent contact to cotton foliage. Two or 3 applications may be needed. May be tank mixed with DSMA or MSMA. May be formulated with MSMA.

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Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Cotton (continued)	
0.48-0.5 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to AK, LA, MS, MI, TN, and TX. Postemergence. Directed spray. Apply to cotton 3 to 6 inches tall. Apply in 10 to 40 gallons of water per acre. For emerged weed control add a compatible surfactant. Leaf fenders or shields may be necessary to prevent contact to cotton foliage. Two or 3 applications may be needed.
[MAI] 0.25 (1 lb/gal SC/L)	May be formulated with MSMA.
1.2-1.6 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to AZ and CA. Postemergence. Layby application. Broadcast or band. For control of germinating or emerged weeds, apply when cotton is at least 12 inches tall (18 inches tall where flood-type nozzles are used) and weeds are less than 2 inches tall. Make 1 application per season. Do not use in the Coachella Valley.
0.8-1.6 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the Blacklands of TX and OK. Postemergence. Layby application. Broadcast or band. For control of germinating and emerged weeds, apply when cotton is at least 12 inches tall and weeds are less than 2 inches tall. Make 1 application per season. Use the lower dosage on loam soils and the higher dosage on clay soils.
1.2-1.6 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the mid-southern and southeast United States. Postemergence. Layby application. Broadcast or band. For control of germinating and emerged weeds, apply when cotton is at least 12 inches tall and weeds are less than 2 inches tall. Make 1 application per season.
0.8-1.2 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to the high plains of TX and NM. Postemergence. Layby application. Broadcast or band. For control of germinating and emerged weeds, apply when cotton is at least 12 inches tall and weeds are less than 2 inches tall. Make 1 application per season. Use the lower dosage on loam and clay soils.
1.2-1.6 (80% WP) (4 lb/gal EC) (4 lb/gal FlC)	Use limited to southwest TX. Do not use in the Rio Grande Valley. Postemergence. Layby application. Broadcast or band. For control of germinating or emerged weeds, apply when cotton is at least 12 inches tall and weeds are less than 2 inches tall. Make 1 application per season.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
15023AA	Pigeon Peas	0.25 ppm Do not graze or feed forage or hay to livestock. General Information: The following rotational crops may be seeded 5 months after applying no more than 2 pounds active ingredient per acre: cabbage, celery, corn, onions, peas, and red beets.
	2-3 (80% WP) 000100-00471 (4 lb/gal EC) 000100-00620	Use limited to PR. Preemergence. Broadcast or band. Apply at planting or immediately after planting before the crop or weeds emerge. Do not use on sandy or loamy sand soils. Make 1 application per year.

TERRESTRIAL NONFOOD CROP

(Ornamental Plants and Forest Trees)

/30097DA	Loblolly Pine (forest) (nursery seedbeds)	N.F. General Information: Total dosages for both preemergent and postemergent applications should not exceed 2 pounds active ingredient per acre.
/30099DA	Longleaf Pine (forest) (nursery seedbeds)	
/30104DA	Slash Pine (forest) (nursery seedbeds)	
	[SLN] 1 (80% WP)	Preemergence. Broadcast. Apply in 20 to 40 gallons of water to dry seedbeds within 48 hours after sowing pine seed and mulching. Incorporate immediately with 0.5 to 0.75 inches of water by sprinkler irrigation.
	[SLN] 1 (80% WP)	Postemergence. Broadcast. Apply to seedlings at least 5 to 6 weeks old.

ERIAL AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
9900300 AAAAAAA	Tank Mix	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton

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PROMETRYN

Listing of Registered Pesticide Products by Formulation

&095.0001 95% technical chemical
  prometryn (080805)
    002749-00278 046386-00002

&097.0001 97% technical chemical
  prometryn (080805)
    000100-00542

&240.0006 40% wettable powder
  prometryn (080805) plus atrazine (080803)
    000100-00492 002749-00321*
      *scheduled to be suspended

&280.0006 80% wettable powder
  prometryn (080805)
    000100-00471 002749-00188 010163-00092 038652-00002

    (000100-00471) AL780003 AZ840001 LA810023

&244.4012 44.4% (4 lb/gal a.i.) emulsifiable concentrate
  prometryn (080805)
    000100-00620 002749-00503 010163-00094

    (000100-00620) AZ840002

&245.4114 45.41% (4 lb/gal a.i.) flowable concentrate
  prometryn (080805)
    001812-00274

&208.4015 8.4% (1 lb/gal a.i.) soluble concentrate/liquid
  prometryn (080805) plus monosodium methanearsonate (013803)
    000100-00495

9999999 State Label Registration

  AZ Reg. No.
    010163-06398

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PROMETRYN

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
080803	--	atrazine
013803	MSMA	monosodium acid methanearsonate

— Use EPA Acceptable Common/Chemical Name

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PROMETRYN

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
013802	DSMA	disodium methanearsonate
108501	pendimethalin (ANSI)	N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine
013803	MSMA	monosodium acid methanearsonate
036101	treflan	trifluralin

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EPA Index to Pesticide Chemicals

PROMETRYN

Auxiliary Documentation

SLN	Cancellation Date
OH810012	11/85

Registration Number 010155-00014 does not contain prometryn (080805) as an active ingredient.

Registration Number 000100-00492 could not be located at EPA and therefore was extracted from the fiche.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Prometryn Standard

MRID	CITATION
00022855	Esser, H.O.; DuPuis, G.; Ebert, E.; et al. (1974) s-Triazines. Pages 129-208, In Without Title. By ? N.P. (Also in unpublished submission received Oct 7, 1977 under 100-566; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:231969-C)
00023213	Muller, P.W.; Payot, P.H. (1966) Fate of 14C-Labelled Triazine herbicides in plants. Pages 61-70, In Isotopes Weed Research: Proceedings of IAEA Symposium; 1965-66, Vienna, Austria. N.P. (Also in unpublished submission received Jul 1, 1971 under unknown admin. no.; submitted by Shell Chemical Co., Washington, D.C.; CDL:221995-R)
00023280	Mattson, A.M.; Solga, J. (1966) The Determination of Atrazine, Simazine and Prometryne in Cow's Milk by Gas Chromatography. Method dated Nov 11, 1966. (Unpublished study received Jul 15, 1968 under 7F5034; submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:092912-A)
00024378	Best, J.A.; Weber, J.B.; Monaco, T.J. (1975) Influence of soil pH on s-Triazine availability to plants. Weed Science 23(5): 378-382. (Also in unpublished submission received Jul 19, 1978 under 201-403; submitted by Shell Chemical Co., Washington, D.C.; CDL:234470-AD)
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00027330 Gemma, A. (1970) Determination of Prometryne, G-11354, and GS-26831 Residues in Cotton and Soybeans by Gas Chromatography. Method No. AG-150 dated Oct 29, 1970. (Unpublished study received Dec 12, 1970 under 100-471; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:000464-C)

00034043 Motko, L.; Alamo, A.; Agamalian, H. (1966) Residue Data Summary. (Unpublished study received Dec 11, 1972 under 100-471; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:000468-C)

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)

00040692 McCann, J.A. (1970) Primaze 80 W: Bluegill (Lepomis macrochirus): Test No. 229. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, unpublished study; CDL:129814-A)

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00055672 Ciba-Geigy Chemical Corporation (1971) Metabolism of s-Triazine Herbicides. (Unpublished study including letter dated Dec 29, 1971 from J.R. Forsythe to Harold G. Alford, received Dec 29, 1971 under 100-437; CDL:231915-A)

00056556 Ciba-Geigy Corporation (1975) Residue Data--Tolban in Cotton. (Compilation; unpublished study received Apr 29, 1976 under 100-523; CDL:224722-A)

00060314 Kapp, R.W. (1975) Final Report: Acute Oral Toxicity Study in Rats: Project No. M915-106. (Unpublished study received Dec 19, 1977 under 33660-5; prepared by Hazleton Laboratories America, Inc., submitted by Industria Prodotti Chimici, S.p.A., Novate Milanese, Italy; CDL:232506-A)

00060315 Kapp, R.W. (1975) Final Report: Acute Dermal Toxicity Study in Rabbits: Project No. 915-107. (Unpublished study received Dec 19, 1977 under 33660-5; prepared by Hazleton Laboratories America, Inc., submitted by Industria Prodotti Chimici, S.p.A., Novate Milanese, Italy; CDL:232506-B)

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00060646	Sachsse, K.; Bathe, R. (1976) Acute Oral LD50 in the Rat of Technical G 34161: Project No. Siss 5540. (Unpublished study received Dec 29, 1977 under 100-542; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:232550-G)
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00065048	Ciba-Geigy Corporation (1981) Residue Tests with Cotton. (Compilation; unpublished study received Apr 28, 1981 under 100-597; CDL:070049-B)
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00070686	Beliles, R.P.; Scott, W.; Knott, W. (1965) Prometryne: Safety Evaluation on Fish and Wildlife (Bobwhite Quail, Mallard Ducks, Rainbow Trout, Sunfish, Goldfish). (Unpublished study received Dec 29, 1977 under 100-542; prepared by Woodard Research Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:232551-B)
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00093338	Richman, B.Q. (1964) Report to Geigy Research Laboratories: Metabolic Fate of C"14t-Prometryne--Albino Rats. (Unpublished study received Nov 26, 1966 under 7F0559; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:090697-G)
00093339	Ryskiewich, D.P. (1965) Metabolism of Propazine and Prometryne in Rats. Ardsley, N.Y.: Geigy Chemical Corp. (Technical bulletin, Feb 11; also in unpublished submission received Nov 26, 1966 under 7F0559; submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:090697-H)
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OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products).

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________________ Date ________________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

			I am complying with data requirements by		
Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2000-0468
Expiration Date 5/31/86

ATTACHMENT D

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________________

Registrant's Name: ____________________

and Address: ____________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient named under FIFRA sec. 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product,

OR

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________
and their registration number(s) is/are ____________________

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA sec. 3(c)(2)(B).

Registrant's authorized representative: ____________________
Signature

Dated: ____________________ ____________________
(Typed)